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Atty. Docket No. ACS 52008 (18161)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

jc515 U.S. PTO 09/476689 12/30/99

Box PATENT APPLICATION
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Sir:
Transmitted herewith for filing is the patent application of

Inventors: Kent C. B. Stalker
For: DEVICE FOR, AND METHOD OF, BLOCKING EMBOLI IN VESSELS SUCH AS BLOOD ARTERIES

Enclosed are:

[X] Nine (9) pages of specification
[X] Four (4) pages of claims
[X] One (1) page of Abstract
[X] Three (3) sheets of drawing(s) [ ] Formal [X] Informal
[ ] Declaration or oath
[X] This application is being filed under 37 CFR 1.53(d) without a signed Declaration or filing fee.
[ ] A certified copy of a _____ application.
[ ] An associate power of attorney.
[ ] Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is (are attached).
[ ] Preliminary Amendment
[ ] Information Disclosure Statement
[ ] Form PTO-1449 and copies of documents listed thereon.
[ ] An assignment of the invention to ADVANCED CARDIOVASCULAR SYSTEMS, INC.
[ ] is attached. A separate [ ] "Cover Sheet for Assignment Accompanying New Patent Application" or [ ] Form PTO 1595 is also attached.
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The filing fee has been calculated below:

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BASIC FEE		
TOTAL CLAIMS	12 - 20 =	* -0-
INDEP. CLAIMS	2 - 3 =	* -0-
MULT.DEP. CLAIMS		
ASSIGNMENT RECORDAL		

SMALL ENTITY RATE	FEE
	$ 380
x $ 9	$
x $ 39	$
+ $130	$
$ 40	$
TOTAL	$

LARGE ENTITY RATE	FEE
	$ 690
x $ 18	$
x $ 78	$
+ $260	$
$ 40	$
TOTAL	$ 690

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Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

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APPLICATION

of

KENT C.B. STALKER

for

UNITED STATES LETTERS PATENT

on

DEVICE FOR, AND METHOD OF, BLOCKING EMBOLI IN VESSELS SUCH AS BLOOD ARTERIES

Docket No. ACS 52008 (18161)

Sheets of Drawing Figures: Three (3)

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DEVICE FOR, AND METHOD OF, BLOCKING EMBOLI IN VESSELS SUCH AS BLOOD ARTERIES

BACKGROUND OF THE INVENTION

This invention relates to a device for, and methods of, preventing emboli from a lesion in a vessel from passing through the vessel. The device and method of the present invention are especially adapted to be used in preventing emboli in blood from passing through a vessel such as an artery.

In recent years, numerous procedures have been adapted for expanding blood vessels (e.g. arteries), at the positions of lesions in the blood vessels, so that blood can flow through the blood vessels without obstruction from the lesions. In the process of expanding such blood vessels at the positions of the lesions, emboli may become detached from the lesions and enter the bloodstream and subsequently migrate through the patient's vasculature to cut off or reduce the amount of oxygenated blood being supplied to sensitive organs such as the brain, which may induce trauma.

Procedures have also been adapted in recent years for preventing embolic debris from flowing through the vessels in the direction of the blood flow. For example, filters have been provided for trapping the emboli. When lesions develop in the carotid artery of a patient, the placement of a filter in the patient's vasculature can somewhat reduce the movement of emboli to blood vessels leading to the patient's brain, thereby preventing strokes from occurring.

Such filters are usually delivered in a collapsed position through the patient's vasculature and are then expanded once in place in the patient's blood vessel to trap the emboli. After emboli have been trapped, the filter is collapsed and removed (with the trapped emboli) from the vessel. Unfortunately, it is possible for some of the trapped emboli to escape from the filter during the time that the filter is being collapsed and/or removed from the blood vessel. When an interventional procedure is being

performed in a carotid artery, even a trace release of emboli can be damaging. For these reasons, attempts to treat lesions in the carotid arteries have been somewhat limited due to the danger presented if all of the embolic debris is not collected during the procedure.

Therefore, in light of the above, it would be desirable for a device and method which can be utilized to treat an occluded vessel and trap any emboli that may be formed during the vascular procedure. Such a device and method must also prevent the emboli from escaping from the filter during the time that the filter is being collapsed and/or removed from the blood vessel (e.g. the carotid arteries). Although considerable progress has been made in recent years in providing a satisfactory filter, it would still be desirable to provide a filter which is simple, cost efficient and trustworthy in construction, and is easy to deploy and remove from the patient's vasculature with little or no adverse impact or immulogical response to the patient.

SUMMARY OF THE INVENTION

The present invention is directed to a filtering device for trapping and removing emboli from a body vessel (e.g. an artery). In one embodiment, the filtering device includes a catheter portion and a filtering portion disposable in the vessel at a position downstream from a lesion formed within the vessel. The filtering device includes a filtering member made from a resilient material having properties of passing fluid (e.g. blood) while blocking the passage of emboli in the fluid. This material may be selected from a group consisting of blood filter material and a braided/woven biocompatible material with the properties specified above. The inner end of the filtering member is attached to an inner shaft which provides for the disposition of the filtering portion of the device in the vessel at the position past the lesion and for the withdrawal of the filtering portion as well.

A directional member, attached to the filtering member, has a length extending at least to the vessel wall. This directional member can be made from a pliable and elongatable material with properties of blocking fluid and emboli passage. The directional member is disposed to direct the fluid and any emboli in the fluid into the filtering member. The filtering and directional members generally are disposed at an acute angle relative to the shaft. The directional member is designed to create a deep pocket which is used to trap the emboli while allowing the fluid to pass there through to downstream vessels. In one particular embodiment, the directional member has a conical shape which acts much like a parachute when deployed in the fluid flow. The directional member opens up when subjected to the fluid flow and remains in a fully deployed position to partially occlude the vessel, due to fluid build proximal to the directional member. The filtering member located within the deep pocket formed by the directional member provides the filtering media for trapping the emboli. In this fashion, the directional member is designed to channel all fluid and emboli into the deep pocket to allow the filtering member to perform the necessary filtration. The design of the deep pocket helps to retain the emboli deep within the filtering device, sufficiently past the inlet opening of the directional member. As a result, there is a less possibility that trapped emboli will "backflow" into the artery as the filtering portion of the device is being collapsed and removed from the patient's vasculature.

An interventional device, such as an expandable member (e.g., a balloon catheter) and a stent, can be disposed in the vessel to treat the lesion and open the vessel at the lesion position. Any suitable interventional device can be used with the present invention. After the interventional device has performed the procedure, it is collapsed and removed from the vessel. Emboli created during the interventional procedure are released into the fluid flow (e.g. bloodstream) and are trapped within the deep pocket formed by the directional member and filtering member.

In one aspect of the invention, the catheter portion of the filtering device includes an outer sheath or sleeve which extends co-axially over the filtering portion of the device. The filtering portion can be deployed from the confides of the sheath by simply moving the inner shaft of the catheter portion in an outward direction from the sheath, or by retracting the sheath, or a combination of both. Once the inlet opening of the directional member is deployed in the fluid flow, it will expand outwardly (like a deployed parachute) within the vessel. Restraining wires, attached to the directional member near its inlet opening extend along the catheter portion to a location outside the patient. When the device is to be collapsed and removed from the patient, the physician simply retracts these wires to collapse the directional member and draw at least a portion of the directional member (including the inlet opening) back into the lumen of the outer sheath. This helps prevent backflow of trapped emboli into the vessel. Any trapped emboli which is capable of backflowing from the filtering portion will now be trapped within the inner lumen of the sheath and will not be discharged into the vessel. Thereafter, the entire device can be removed from the patient with little risk of losing any trapped emboli.

These and other advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view, primarily in section, of a preferred embodiment of device for trapping and removing emboli produced in a vessel during an interventional procedure, along with an interventional device which includes a stent delivery catheter and a self-expanding stent.

FIG. 2 is an enlarged fragmentary elevational view, primarily in section, of the preferred embodiment of FIG. 1 showing in additional detail the filtering device in an expanded position against the wall of the vessel.

FIG. 3 is an enlarged fragmentary elevational view, primarily in section, of the filtering device in the expanded position and additionally shows the stent deployed against the wall of the vessel in the area of treatment which results in the creation of emboli that are released into the fluid flow of the vessel.

FIG. 4 is an enlarged fragmentary elevational view, primarily in section, of the filtering device in the collapsed position with trapped emboli contained therein after the expansion of the stent against the wall.

FIG. 5 is an enlarged fragmentary elevational view, primarily in section, showing the filtering device being withdrawn from the vessel.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A first preferred embodiment of a filtering device made in accordance with the present invention, generally indicated at 10, is shown in FIGS. 1 - 5 of the drawings. The filtering device 10 is adapted to be disposed in a blood vessel 12 to pass the blood in the vessel and block the passage of emboli 14 (FIG. 3) in the blood. The filtering device 10 includes a catheter portion 16 which is designed to deploy a filtering portion 18 in the vessel 12 to trap and remove emboli 14 from the vessel. The emboli 14 are produced when the vessel 12 is treated at the position of a lesion 20 during an intervention procedure such as, a balloon angioplasty procedure, a stenting procedure, an atherectomy procedure and the like. The present invention is designed to collect and remove such

embolic debris from the artery to prevent the blockage of the smaller vessels downstream from the area of treatment. The system 10 is especially adapted to prevent blockage of small blood vessels leading to the brain which, if blocked, can result in the patient suffering a stroke.

An interventional device, such as a stent delivery catheter 22 and a self-expanding stent 24, can be utilized to treat the lesion 20 and open up the artery 12 to increase blood flow therethrough. This stent delivery catheter 22 and the stent 24 may be constructed in a manner well known in the art. The delivery catheter 22 and the stent 24 may be disposed at the position of the lesion 20 as shown schematically in FIG. 1. The delivery catheter 22 includes an inner tubular member 26 onto which the compressed or collapsed stent 24 is mounted. This inner tubular member 26 includes an inner lumen 28 which allows the stent delivery catheter 22 to be disposed over the catheter portion 16 of the device 10 in a co-axial arrangement. This allows the stent delivery catheter 22 to be delivered to the area of treatment using over-the-wire techniques. The stent delivery catheter 22 includes an outer restraining sheath 30 which extends over the inner tubular member 26 in a co-axial arrangement and is used to restrain the collapsed stent 24 until it is ready to be deployed. Both the outer retraining sheath 30 and inner tubular member 26 have proximal ends (not shown) which extent outside of the patient. In use, the physician moves the proximal ends to retract the distal end 32 of the restraining sheath 30 the necessary distance to expose and deploy the self-expanding stent 24. Once the stent 24is positioned across the lesion 20, the restraining sheath 30 can be retracted to expose the stent 24 and allow it to self expand against the wall 34 of the vessel 12. The opening in the vessel 12 is maintained by the stent 24 even after the delivery catheter 22 is withdrawn from the vessel.

The filtering portion 18 of the device 10 is constructed to be inserted into the vessel 12 at a position past the lesion 20 in the direction of the fluid flow (i.e. downstream from the lesion). The filtering portion 18 includes a filtering member 36

disposed at the interior of the vessel 12. The filtering member 36 may be made from a material having properties of passing the fluid such as blood and of blocking the passage of the emboli 14 in the blood. For example, the material for the member 12 may be selected from a group consisting of blood filter material and a braided/woven biocompatible material. Commercially available materials such as Gortex also can be used . The filter can be made from polymeric or nylon material which has openings of a desired sized formed therein to allow fluid to pass but to capture emboli of a desired size. The distal end 38 of the filtering member 36 is attached to an inner shaft 40 which provides for the disposition of the filtering portion 18 in the vessel 12 at the position past the lesion 20. The shaft 40 may include an inner lumen (not shown) which allows the catheter portion 16 to be delivered into the patient's vasculature over a guidewire (not shown) using over the wire techniques. A directional member 42 is attached to the filtering member 36, preferably at the outer periphery of the filtering member 36. The directional member 42 may be made from a material having properties of blocking the passage of the fluid such as blood and the emboli in the blood. The directional member 42 is preferably highly pliable and/or highly elongatable. This provides for the inlet opening 44 of the directional member 42 to be disposed tightly against the wall 34 defining the vessel 12, thereby preventing fluid and emboli from leaking along the wall 34. The directional member can have a cone or cone-shape like construction, although the directional member can take on other shapes as well. The directional member 42 is disposed relative to the filtering member 36 to direct the fluid and emboli in the vessel 12 to the filtering member 36. The filtering member 36 and directional member 42 form an acute angle with the shaft 40 and the wall 34 of the vessel 12 to create a deep pocket 46 which is used to trap the emboli while allowing the fluid to pass there through to downstream vessels. The directional member 42 opens up when subjected to the fluid flow and remains in a fully deployed position to partially occlude the vessel, due to fluid build proximal to the directional member. The filtering member 36 located within this

deep pocket 46 provides the filtering media for trapping the emboli. In this fashion, the directional member is designed to channel all fluid and emboli into the deep pocket 46 to allow the filtering member to perform the necessary filtration. The design of the deep pocket 46 helps to retain the emboli deep within the filtering device, sufficiently past the inlet opening 44 of the directional member 42. As a result, there is a less possibility that trapped emboli will "backflow" into the vessel as the filtering portion 18 of the device 10 is being collapsed and removed from the patient's vasculature.

The filtering device 10 is used during vascular intervention, in particular preferably during carotid artery angioplasty and stenting. The filtering device 10 is advanced in the artery so that the stent 24 is disposed at the lesion 20 with the filtering portion 18 disposed past the lesion 20 in the direction of the fluid flow. During the delivery of the filtering portion 18 to the position past the lesion 20, the filtering portion 18 may be housed within a sheath 50, which forms a part of the catheter portion 16 of the device 10, so as to have a constricted (or contracted) relationship. The sheath 50 is then moved in a direction away from the filtering portion 18 as indicated by arrow 52 in FIG. 2. This causes the directional member 42 to expand outwardly so that the member engages the wall 34 of the vessel 12. The stent 24 is then expanded against the wall 34 of the vessel 12 to open the artery at the position of the lesion 20. Any emboli 14 produced as a result of the expansion of the stent 24 against the lesion 20 flow to the filtering portion 18. The directional member 42 directs the fluid and emboli 14 to the filtering member 36 which passes the fluid but captures the emboli 14.

When emboli 14 have been trapped by the filter, the stent delivery catheter 22 is withdrawn in the vessel 12. Any emboli 14 produced by the withdrawal of the stent delivery catheter will likewise be trapped by the filtering portion 18. The withdrawal of the stent delivery catheter 22 is indicated by a hollow arrow 54 in FIG. 3. The filtering device 10 includes restraining wires 56, attached to the directional member 42 near its inlet opening 44, which extend along the catheter portion 16 to a location outside the

patient. When the filtering portion 18 is to be collapsed and removed from the patient, the physician simply retracts these restraining wires 56 to collapse the directional member 42 and draw at least a portion of the directional member (including the inlet opening 44) back into the lumen 58 of the outer sheath 50. This helps prevent backflow of trapped emboli into the vessel. Any trapped emboli which is capable of bacflowing from the filtering portion will now be trapped within the inner lumen 58 of the sheath 50 and will not be discharged back into the vessel 12. Thereafter, the entire device 10 can be removed from the patient with little risk of losing any trapped emboli 14. The removal of the device 10 from the vessel 12 is indicated by hollow arrows 60 in FIGS. 4 and 5. While only two restraining wires are shown in the figures, any number of wires can be utilized to help collapse the directional member 42 and retract it back into the inner lumen 58 of the sheath 50. Other means for collapsing the directional member 42 also can be used without departing from the spirit and scope of the present invention.

The catheter portion 16 of the filtering device 10 made be made from suitable polymeric materials well known in the art. The restraining wires can be made from suitable metals or polymeric materials which have sufficient axial strength so as not to break when being retracted to collapse the directional member. The device 10 can be used in conjunction with current compatible devices such as balloon catheters, stent delivery systems, guide wires, guiding catheters and angiographic catheters.

Although this invention has been disclosed and illustrated with reference to particular embodiments, the principles involved are susceptible for use in numerous other embodiments which will be apparent to persons of ordinary skill in the art. The invention is, therefore, to be limited only as indicated by the scope of the appended claims.

WHAT IS CLAIMED:

1. A filtering device for passing a fluid in a body vessel defined by a wall and for blocking the passage through the vessel of emboli, comprising:

a filtering portion constructed to be disposed in the vessel including a directional member made from a pliable material having properties of blocking the passage of the fluid and the emboli and being expandable by the fluid flow in the vessel to maintain its outer periphery against the vessel wall in order to provide a seal against the passage of the fluid and the emboli through the pliable material, and

a filtering member disposed interiorly of the directional member and made from a material providing for the passage of the fluid and for the blocking of the emboli.

2. The filtering device of claim 1, wherein:

the filtering member is made from a material selected from a group consisting of blood filter material and a braided/woven biocompatible material.

3. The filtering device of claim 1, further including:

a catheter portion having a shaft,

the filtering portion being disposed on the shaft at an interior position on the filtering member.

4. The filtering device of claim 1, wherein

the directional member is disposed at an acute angle relative to the vessel wall.

5. The filtering device of claim 2, wherein:

the directional member is elongated to be disposed at its outer end against the vessel wall,

the directional member is disposed relative to the filtering member to direct to the filtering member the fluid and the emboli received by the directional member,

a catheter portion having a shaft is provided, and

the filtering portion is disposed on the shaft at an interior position on the filtering member.

6. The filtering device of claim 5, wherein:

the filtering portion is disposed at an acute angle relative to the vessel wall and the filtering member is made from a material selected from a group consisting of a blood filter material and a braided/woven biocompatible material.

7. The filtering device of claim 5, wherein:

the catheter portion includes an outer sheath which covers the filtering portion until the filtering portion is to be deployed, the filtering portion being at least partially retractable into the sheath after the filtering portion traps and collects emboli in the vessel.

8. The filtering device of claim 7, wherein:

the catheter portion includes a plurality of restraining wires attached near the inlet opening of the directional member and extending along the length of the catheter

portion, the restraining wires being retractable from a location outside the body vessel to collapse the directional member.

9. The filtering device of claim 8, wherein:

the restraining wires are retractable to draw at least the inlet opening of the directional member into the sheath of the catheter portion.

10. A method of passing a fluid in a vessel while blocking the passage through the vessel of emboli created from a lesion in the vessel, comprising the steps of:

disposing in the vessel, at a position past the lesion in the direction of the fluid flow in the vessel, a filtering device having a filtering assembly having a filtering member made from a material having properties of passing the fluid in the vessel while blocking the passage of the emboli in the vessel and having a directional member made from a material having properties of being deployable by the fluid flow in the vessel to be disposed against the wall of the vessel and of directing the passage of the fluid and the emboli in the vessel into the filtering member; and

disposing in the vessel, at the position of the lesion in the vessel, an interventional device for treating the lesion and opening the vessel at the position of the lesion.

11. The method of claim 10 further including the step of removing the filtering device with any trapped contained in the filtering member from the vessel after the interventional device has treated the lesion.

12. The method of claim 11 wherein the steps of removing the filtering member from the vessel is performed by collapsing the directional member and withdrawing at least a portion of the directional member into a sheath and removing both the sheath and filtering device from the vessel.

ABSTRACT

A filtering device has a directional member and filtering member disposable in a vessel (e.g. blood artery) at a position past a lesion in the direction of fluid flow. The filtering member is made from a resilient material having properties of passing the fluid while blocking the passage of emboli in the fluid. This material may be selected from a group consisting of blood filter material and a braided/woven biocompatible material with the properties specified above. The inner end of the filtering member is attached to a shaft which provides for the disposition of the members in the vessel at the position past the lesion and the withdrawal of the members from the vessel. The directional member has a length extending at least to the vessel wall. The directional member is made from a pliable and elongatable material with properties of blocking fluid and emboli passage. The directional member is deployable within the vessel by the fluid flow in the vessel and directs the fluid in the vessel and any emboli in the fluid into the filtering member. The filtering and directional members are disposed at an acute angle relative to the shaft to create a trapping pocket. Restraining wires attached to the directional member are used to collapse the directional member and draw at least a part of the directional member into an outer sheath to prevent emboli from backflowing into the vessel.

FIG. 1

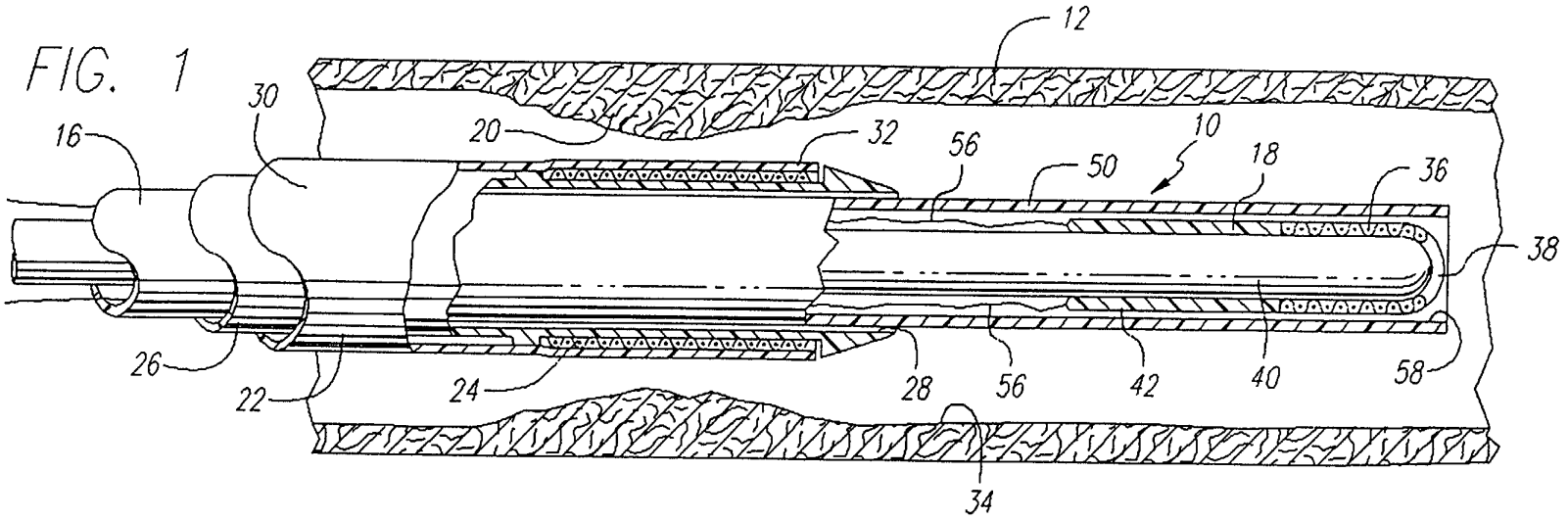
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FIG. 2

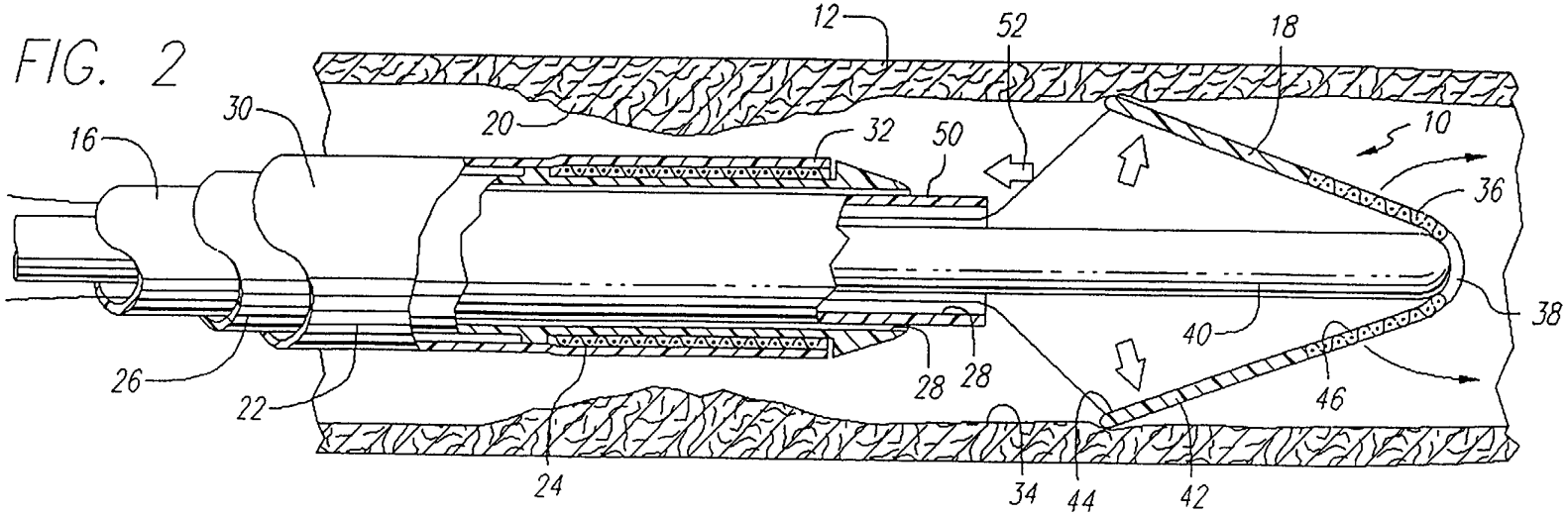
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FIG. 3

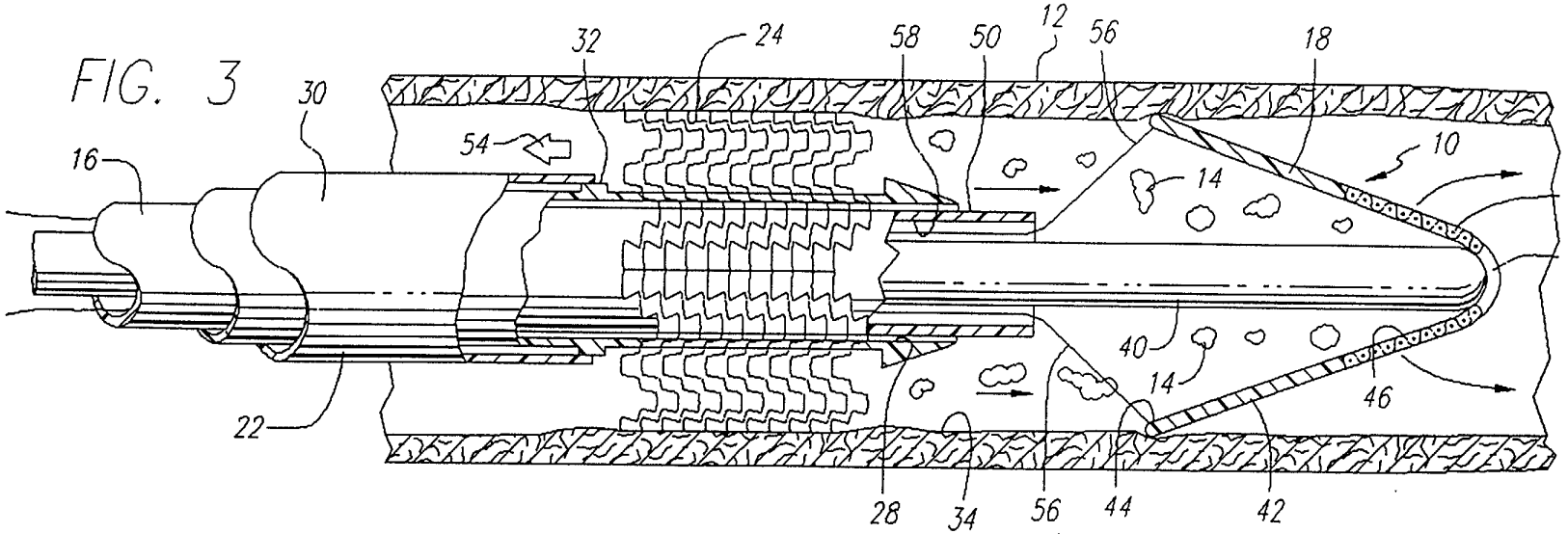
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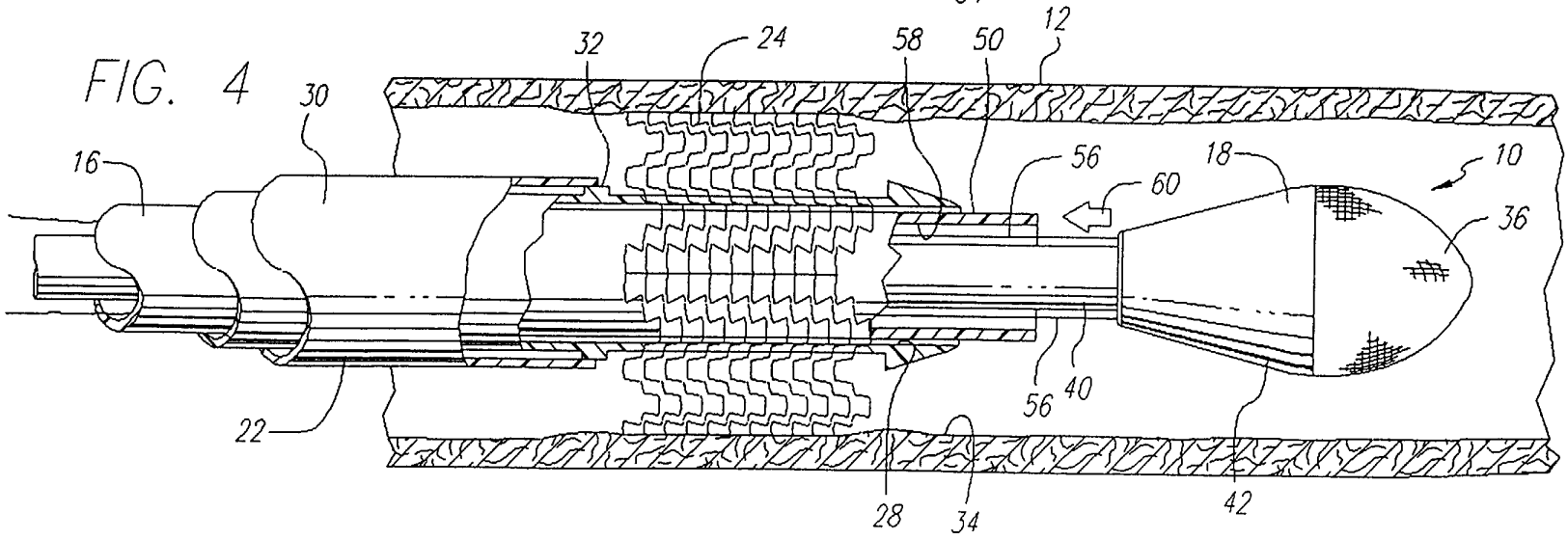
FIG. 4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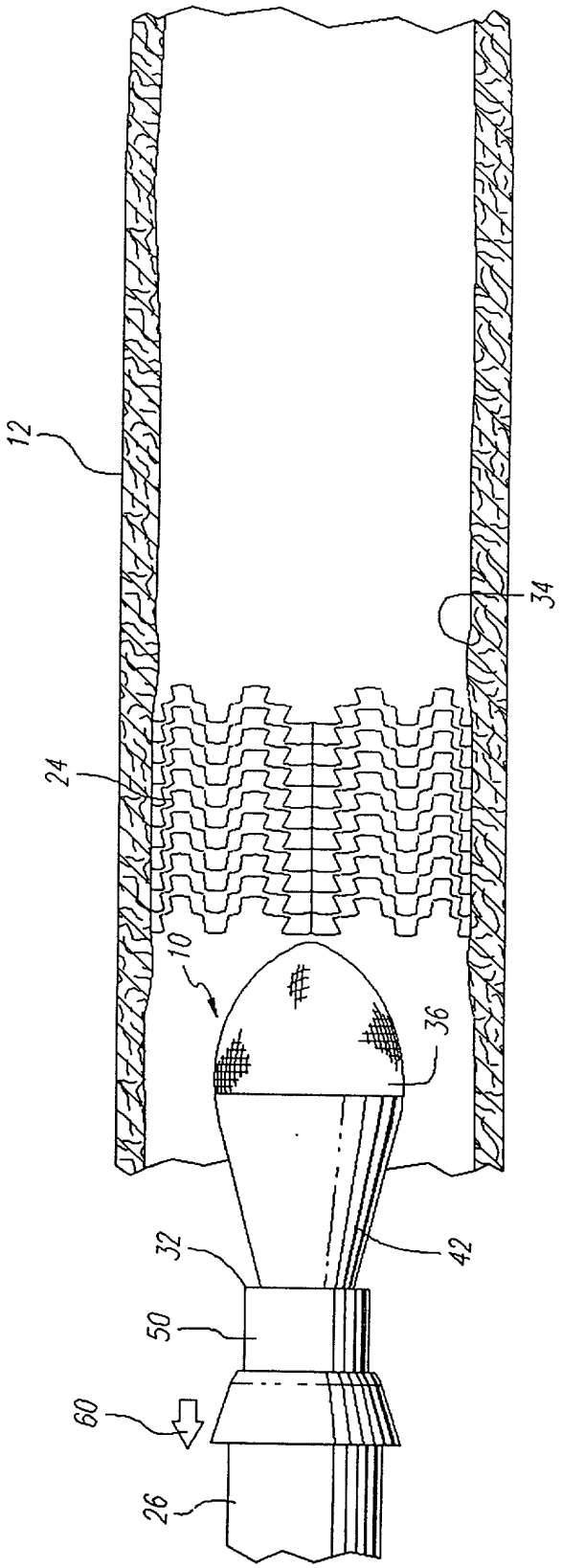

FIG. 5